K121360

510(k) Summary

21 February 2013

FEB 2 7 2013

Cook Biotech Incorporated

Biodesign® ENT Repair Graft

Manufacturer Name: Cook Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Biodesign ENT Repair Graft
Common Name:	Ear, nose and throat synthetic polymer material
Classification Regulations:	Class II, 21 CFR §874.3620 (KHJ)

INTENDED USE:

The Biodesign ENT Repair Graft is intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired. The device is supplied sterile and is intended for one-time use.

DEVICE DESCRIPTION:

The Biodesign ENT Repair Graft is composed of a bioabsorbable, extracellular collagen membrane matrix (Small Intestinal Submucosa, SIS). The Biodesign ENT Repair Graft is similar to its predicate MeroGel™ Control Gel ENT Surgical Dressing (K002972) which is a biomaterial composed of HYAFF®, an ester of hyaluronic acid, a natural occurring constituent of extracellular matrix. The device is available in multilayered sheets with sizes from 1 cm by 2 cm to 20 cm x 40 cm. The Biodesign ENT Repair Graft is a scaffold which becomes infiltrated by the host cells during the body's natural repair process. The Biodesign ENT Repair Graft can be shaped by the physician to the appropriate size for the desired indication.

The Biodesign ENT Repair Graft is similar to its MeroGel predicate in its technology in that it has the ability to be incorporated into the body. The device is packaged in a lyophilized (dried) state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The Biodesign ENT Repair Graft is similar with respect to intended use, materials and technological characteristics to the predicate device in terms of section 510(k) substantial equivalence, as shown biocompatibility testing (conducted in accordance to ISO 10993-1 standards), mechanical, pre-clinical and clinical testing.

Biocompatibility testing

The following biocompatibility tests were performed on sterilized SIS devices (which have already been cleared in multiple applications), which are identical in composition to the Biodesign ENT Repair Graft (according to the ISO 10993-1 standard):

- Genotoxicity
- Direct contact *in vitro* hemolysis
- Cytotoxicity
- Muscle implantation
- Acute intracutaneous reactivity
- Skin irritation
- ISO Sensitization
- Acute systemic toxicity
- Pyrogenicity
- LAL endotoxins
- Subchronic systemic toxicity

The results of these tests provided evidence that the Biodesign ENT Repair Graft meets biocompatibility requirements of the ISO standard.

Mechanical Testing

The Biodesign ENT Repair Graft material was tested for the following:

- Suture retention strength
- Ultimate tensile strength

The results of the mechanical testing provided evidence that the Biodesign ENT Repair Graft provided adequate mechanical strength in its application.

Preclinical Testing

A mouse subcutaneous study confirmed that the Biodesign ENT Repair Graft was able to help maintain tissue separation, is quickly populated with cells, and degrades during cellular ingrowth. This animal study provides evidence that the Biodesign ENT Repair Graft is biocompatible and safe in its application.

Clinical Testing

A clinical study was performed using the SIS material (Surgisis) for nasal septal perforation repair. The clinical study provides evidence that the Biodesign ENT Repair Graft is substantially equivalent to its predicate in nasal and/or sinus procedures.

Substantial Equivalence

See Table 1 for a comparison of the subject device and its predicate.

Table 1 – Substantial Equivalence Comparison

Device	Biodesign ENT Repair Graft	MeroGel™ Control Gel ENT Surgical Dressing
Manufacturer	Cook Biotech Incorporated	Medtronic Xomed
510(k) Number	K121360	K002972
Intended Use	The Biodesign® ENT Repair Graft is intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired. The device is supplied sterile and is intended for one-time use.	MeroGel Control Gel ENT Surgical Dressing is a dressing and/or stent intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use in ear, nose, and throat, head and neck surgical procedures where an open wound dressing material is required including the middle ear and external ear canal following myringoplasty, tympanoplasty, canalplasty, stapes and mastoid surgery, also for use in the nasal and/or sinus cavities following nasal, sinus, and/or throat surgery where separation of tissues or structures is desired.
Material	Small intestinal submucosa Primarily Types I, III, IV and VI collagen (constituents of the extracellular matrix)	HYAFF® (ester of hyaluronic acid, a naturally occurring constituent of the extracellular matrix)
Dimensions	1 cm x 2 cm to 20 x 40 cm	N/A
Thickness	100 µm to 500 µm	N/A

CONCLUSION: The biocompatibility, mechanical, pre-clinical and clinical tests performed on the Biodesign ENT Repair Graft show that the device is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Cook Biotech Incorporated
% Mr. Perry W. Guinn
VP of QA and Regulatory Affairs
1425 Innovation Place
West Lafayette, IN 47906-1000

Re: K121360
Trade/Device Name: Biodesign® ENT Repair Graft
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: February 4, 2013
Received: February 7, 2013

Dear Mr. Guinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121360

Indications for Use

510(k) Number (if known): **K121360**

Device Name: **Biodesign® ENT Repair Graft**

Indications For Use:

The Biodesign® ENT Repair Graft is intended to separate tissue or structures compromised by surgical trauma, help control minimal bleeding, and act as an adjunct to aid in the natural healing process. The device is indicated for use where an open wound dressing material is required in the nasal and/or sinus cavities following nasal and/or sinus surgery where separation of tissues or structures is desired.
The device is supplied sterile and is intended for one-time use.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vasant G. Malshet

Digitally signed by Vasant G. Malshet
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Vasant G. Malshet, 0.9.2342.19200300.100.1.1=13000087851
Date: 2013.02.26 13:13:30 -05'00'